Lilly

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November 3, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Notice - 21 C.F.R. Part 314
180-day Generic Drug Exclusivity for
Abbreviated New Drug Applications
Docket No. 85N-0214

Dear Madam or Sir:

As one of our nation's leading research-based pharmaceutical enterprises, Eli Lilly and Company invests on the order of $1.8 billion annually to discover new medicines that benefit the health and welfare of persons in the U.S. and throughout the world. As a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), Lilly shares the concerns of this organization as they pertain to FDA's proposed regulation interpreting the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"). *See 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications*, 64 Fed. Reg. 42873 (1999) (to be codified at 21 C.F.R. § 314) ("Notice" for purposes of citation and "Proposed Rule" for purposes of discussion). As pointed out by PhRMA in its comments on the Proposed Rule, the Hatch-Waxman Act represents a political compromise that carefully balances the competing interests of innovator drug companies and generic producers. FDA regulations implementing the Hatch-Waxman Act therefore impact substantially the balance between these competing interests. Lilly, like PhRMA members generally, has a strong interest in FDA's Proposed Rule to the extent that it distorts this balance. PhRMA's comments notwithstanding,

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however, Lilly wishes to provide the following additional comments, which underscore what Lilly considers the most salient legal and policy flaws in the "triggering period" provision of the Proposed Rule, for Lilly believes that it is the "triggering period" that disrupts most fundamentally the balance struck by Congress in crafting the Hatch-Waxman Act.

The "Triggering Period" Provision of the Proposed Rule Contravenes Both the Plain Language and Policy Objectives of the Statutory 180-Day Exclusivity Provision

A cornerstone of the Proposed Rules imposes a 180-day "triggering period" during which a triggering event--marketing or a court decision favorable to the first ANDA filer, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)--must occur. According to the Notice, the triggering period guards against prolonged or indefinite delays in bringing generics to market. While this may be so, the proposed shield is merely additive, as the statute already enables generics to market far earlier than was previously possible. But in addition to being additive, the triggering period is also disruptive: it imposes an onerous barrier to just resolution of patent disputes and severely inhibits a generic's incentive to be a first ANDA filer by in many instances rendering the statutory exclusivity period valueless.[1] As such, the triggering period contravenes in two ways the statutory scheme set forth by Congress, in a manner damaging to both innovators and generics. Moreover, the triggering period appears to suffer from virtually the same fatal defect attributed by the D.C. Circuit to FDA's previous "successful defense" requirement, by imposing a nexus between the 30-month stay and exclusivity provisions of the statute that allows exclusivity to lapse before a court decision on a paragraph (IV)-certified patent ensues. *See Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060,1072, 46 USPQ2d 1385, 1394 (D.C. Cir. 1998) ("it is not inconceivable that Congress meant what the statute says, i.e.,

[1] As PhRMA notes in its comments on the Proposed Rule, FDA has recognized that premature triggering of the exclusivity period would "render the exclusivity valueless." *Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions; Final Rule,* 59 Fed. Reg. at 50,352.

that the second application would have to wait for the first lawsuit to finish."). For these reasons, FDA should remove the triggering period from the Proposed Rules.

A. The Triggering Period Fails to Appreciate the Statutory Scheme Enacted by Congress

The triggering period fails to appreciate that the plain language of the Hatch-Waxman Act already fashions a procedure whereby generics are afforded an opportunity to market much earlier than was previously possible. First, the Act dispenses with the requirement that generics submit their own safety and efficacy data for a listed drug, allowing them to rely on innovator data instead. Second, the Act overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir. 1984), and thus allows generics to experiment with patented drugs to obtain bioequivalence data without apprehension of suit. Third, the Amendments allow courts to shorten the imposed 30-month stay in order to prevent delaying tactics. Taken together, these provisions hasten considerably the bringing of generics to market.

The triggering period likewise fails to appreciate that the Hatch-Waxman Amendments afford carefully balanced protections both to innovator-patentees--by providing a 30-month stay upon the filing of suit, *see* 21 U.S.C. § 355(j)(5)(iii)--and to first-ANDA-filer-generics--by providing an enormous incentive to bear the risks of suit, in the form of a virtually unconditional eligibility for 180 days of market exclusivity, *see* 21 U.S.C. § 355(j)(5)(iv).

Provisions (iii) and (iv) are independent and serve altogether different purposes. They represent a careful balance struck by Congress to accommodate the concerns of both innovators and generics. The Proposed Rule, however, impose a nexus between provisions (iii) and (iv) that disrupts this balance by curtailing both the statutory protections accorded the patentees and the statutory incentives accorded the generics. This disruption is contrary to both the spirit and letter of the statute.

B. The Triggering Period Imposes an Overwhelming Burden on the Just Resolution of Patent Disputes

The 30-month stay provision protects innovator-patentees by imposing risk upon first ANDA filers, who must bear the costs of litigation during this period without the benefit of immediate revenue from the marketing of generic drugs. In return for this risk, first ANDA filers receive 180 days of market exclusivity. By imposing a triggering period, however, FDA will curtail severely the opportunity for a generic competitor to ever benefit from statutory market exclusivity, for the generic competitor must make its case--all the way through to appeal--within 30 months or forever lose this statutory benefit within six months thereafter. This restriction on eligibility for market exclusivity exerts enormous pressure on first ANDA filers to obtain a favorable and final court decision within 30-months of the filing of suit. But patent cases are complex; their just resolution usually requires more than 30 months, especially when validity is at issue, as is often the case. Patents are, of course, presumed valid, and first ANDA filers bear the burden of proving invalidity by clear and convincing evidence. *See* 35 U.S.C. § 282. The incentive provided by the proposed triggering period to rush through litigation works to the detriment of both the first ANDA filer and the patentee. The first ANDA filer must execute its litigation strategy with undue haste, notwithstanding its heavy burden of proof on validity issues. The patentee, as innovator, virtually always has many more documents (often millions of pages of them) and deponents than the ANDA filer, and therefore must bear the enormous burden of complying with onerous discovery in short order, as well as prepare to defend its patents with undue haste. Under the current rules, it is already a daunting and enormously expensive task for an innovator moving at full speed and without delay to prepare a defense to usually unanticipated attacks on its patent while complying with voluminous discovery requests. The triggering period seems to ignore the presumption of validity of patents and imposes a virtually impossible burden on both plaintiff and defendant to conclude litigation prematurely.

C. The Triggering Period Dismantles the Carefully Balanced Incentive System Set Forth by the Statute

Nothing in the statute indicates that Congress ever intended the 30-month stay (or any other period, for that matter) to operate as a limit on either litigation or on eligibility for market exclusivity. Quite to the contrary, the stay operates merely as a limit on the statutory bar to generic marketing. It is ultimately a permissive, not a restrictive, provision. As pointed out in PhRMA's comments on the Proposed Rule, the Notice nevertheless asserts that the length of the triggering period derives from the statutory provision governing 180-day exclusivity. According to the Notice,

> [t]his provision quite clearly allows (and Congress, therefore, presumably contemplated) the possibility of a 180-day period during which there is no generic drug product on the market. This would occur when the running of the 180-day period of exclusivity has begun with a court decision finding the patent invalid, unenforceable, or not infringed, but the applicant that has the exclusivity does not begin marketing its product because it is not approved or for another reason.

Notice, 64 Fed. Reg. at 42,878. This rationale appears to equate Congress's permission to delay marketing of other generics for the benefit of a first applicant with a 180-day period that severely limits the first applicant's ability to ever reap this benefit.[2]

In establishing the period of exclusive generic marketing, Congress created a statutory scheme whereby a first ANDA filer can choose whether to market before or after it successfully challenges a patent, without having to worry about forfeiting market exclusivity. By statute, the 180-day exclusivity period ensues irrespective of the time when the first ANDA filer executes this choice, and independently of the 30-month stay provision. FDA's previous attempt to limit this choice was held to contravene the plain

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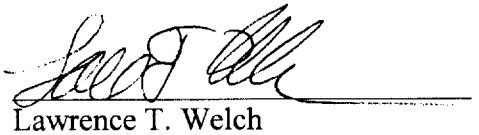
2 Again as pointed out in PhRMA's comments on the Proposed Rule, the choice of 180 days for the length of the triggering period is arbitrary, as evidenced by the proposal for a reduced triggering period of 60 days in some cases.

meaning of the statute. *See Mova,* 140 F.3d at 1072, 46 USPQ2d at 1394 (stating that Congress may well have required a second applicant "to wait for the first lawsuit to finish"). It is difficult to see how the proposed 180-day triggering period overcomes the fundamental defect in FDA's prior scheme identified by the *Mova* court. The 180-day triggering period establishes a nexus between the 30-month stay and the 180-day market exclusivity period that is altogether absent from the statute. By imposing this nexus, FDA severely burdens both parties to the litigation and limits substantially the opportunities for a first ANDA filer to obtain exclusivity. In so doing, FDA's Proposed Rule decreases the statutory protections afforded innovator-patentees and increases the risks faced by a first ANDA filer, thereby decreasing the incentive to file a first ANDA. As such, FDA's proposed rule alters substantially the careful balance of incentives created by Congress and therefore fails to conform to either the letter or spirit of the statutory regime.

CONCLUSION

Lilly appreciates this opportunity to comment on the Proposed Rule. For the reasons presented here, Lilly urges respectfully that the FDA revise the Proposed Rule to comply with the statutory language and policy objectives of the Hatch-Waxman Act by abandoning the suggested "triggering period" imposed upon first ANDA filers subjected to paragraph (IV) certification suits by innovator-patentees. In so doing, Lilly believes that the careful balance struck by Congress in passing the Hatch-Waxman Act will be duly preserved.

Sincerely,



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